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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,770

Applicant(s)

BROKISH, HAROLD A.9

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 0123.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-33 are pending and are under examination.

Information Disclosure Statement

No IDS is filed with this application.

Objections

Claims 1, 17, and 19 (and dependents 2-16, 18 and 20-33) are objected to for failing to recite complete ATCC accession information. The ATCC Accession no must be filled in as appropriate.

In claim 11, " second said parent" should be changed to --- said second parent---

In claim 28, "corn plants" should be changed to the corn plant.

The specification is objected to because of the following: the statement of deposit in the specification, page 33, does not comply with the deposit requirement set forth in 37 CFR 1.801-1.809. The deposit statement must be amended to include the deposit accession no of the inbred line.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are indefinite in the recitation "KW7648". Since the name "KW7648" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "KW7648" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Amending claims 1, 17 and 19 to recite the ATCC deposit number in which seed of corn inbred line KW7648 has been deposited would overcome the rejection.

Claim 5 is indefinite in the recitation of "wherein said plant is male sterile" because the claims from which claim 5 depends are not drawn to a male sterile plant.

In claim 8, "the.... or protoplasts" lacks antecedent basis. Also "the cells or protoplasts of the tissue culture being " is unclear. It is suggested that "the cells or protoplasts of the tissue culture being " is replaced with ---wherein the cells or the protoplasts of said cells are produced---.

Claims 19 -25 are indefinite because the metes and bounds of what is retained in "KW7648-derived" corn plants or parts thereof are unclear. Would "derived" mean "isolated" or "progeny" or something else? What is encompassed in the derived plants is unclear. Replacing "KW7648-derived" with ----F1 hybrid----can obviate this rejection.

Claims 20, 23, 25, and 29 are indefinite in the recitation of " below average" and "above average", which are relative terms lacking comparative basis. It is unclear what the average is.

Claim 30 is indefinite for lacking defined method steps.

Claim 31 is indefinite in the recitation of "The corn plant breeding program of claim 30" which lacks antecedent basis. Claim 30 is drawn to a method for developing a corn plant rather than a breeding program.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 33 of the specification indicating Applicant's intention to make an enabling deposit of the claimed invention with ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is required for enablement purpose.

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If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 C.F.R. 1.808-1.809 for additional explanation of these requirements.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claims 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is drawn to "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by back crossing or other traditional means, and methods of using these plants.

Applicant has not disclosed or provided guidance for the introgression of a gene trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or the morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

For example, Hunsperger et al (US Patent No. 5, 523, 520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected transfer gene trait (column 3, lines 26-46). Kraft et al (Theor. Appl. Genet. 2000, vol. 101, pp. 323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and such that effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed

for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See, Eshed et al (Genetics, vol. 143, pp1807-1817, 1996) who teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effect are not common in corn breeding materials, such that one or more transgenes can be transferred from one genetic background to another.

Therefore, given the lack of guidance in Applicants' specification regarding transfer and expression of genes by backcrossing in Applicant's corn line while retaining the other desirable genotypic and phenotypic characteristics, the state of the art, the unpredictability inherent in single gene transfer, and lack of working examples, one skilled in the art would not be able to make and/or use the invention, without undue experimentations.

Written Description

Claims 12-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. Claims 12-25 are drawn to corn plants of an undisclosed number of generations that are only known to have at least one ancestor of KW7648 corn plant, KW7648-derived or further derived plants obtained by repeated crossing of a KW7648 corn plant with itself or with another non-KW7648 corn plant by a number of generations, and a method for producing said derived and further derived corn plants. These are genus claims. Applicant only describes inbred corn line KW7648 having specific combination of genotypic and phenotypic characteristics that distinguish the line from other corn lines. Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds of claims 12-16 produced by crossing the inbred corn line KW7648 with another unidentified corn plant. No specific morphological or genotypic characteristics that distinguish F1 hybrid corn plants/seeds from other corn plants and seeds are described. Since Applicant has not described even F1 generation plants, methods for using F1 or other hybrid plants of claims 19, 21 and 24 to produce subsequent generation plants of claims 20, 22-23 and 25 are similarly not described. Furthermore, since Applicant has not described the breeding partners involved in crossing with the exemplified plant, or the resultant product, Applicant also has not described methods for using the products in subsequent generations of outcrossing to uncharacterized breeding partners, or the resultant products of said multiple outcrosses as claimed in claims 29-32. The only characteristics recited for the claimed plants are the expression of the combination of at least two traits

which were described with relative terms that lack comparative basis (see rejection under 112, 2nd paragraph).

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". *Id.* In the instant application, the disclosure of a single corn inbred line, KW7648, does not provide adequate written description for the claimed genus, F1 or subsequent generation plants or a method for using them to produce KW7648-derived or further derived plants, wherein only one ancestor of the plant is known to be KW7648, and the rest of the ancestors are unknown. In addition, because various breeding techniques (claims 30-31) and a number of uncharacterized breeding partners and breeding generations have been employed, substantial variation in structure and phenotypes are expected among the resultant plants.

Claims 26-28 are included in the rejection because Applicant has not described a multitude of non-exemplified transgenes or their phenotypic effects in particular corn genetic background. In addition, the claims do not characterize the sequence or identity

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of the transgenes or recite phenotypic effects. Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Foley (US 5, 973, 239).

Foley teaches inbred corn line designated as LH265 and a method for producing hybrid plants and seeds by crossing the LH265 line with another corn line, F1 hybrid and subsequent generation corn plants. The cited reference teaches breeding methods such as pedigree and recurrent selection breeding methods and backcrossing to transfer specific desirable trait between plants. The corn plants of the instant invention and those of the prior art share agronomic and morphological characteristics such as leaves with medium green color, red cob, yellow anther and green glume, yield, stalk

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and root quality (columns 6-9; Table 1; claims). Alternatively, if the claimed plants, plant parts, and seeds of KW7648 are not identical to LH265, then it appears that LH265 only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to LH265. The reference also teaches tissue culture of regenerable cells of LH265, and plants regenerated from the tissue culture having LH265 genotype (column 2, lines 48-65; claims), and method of transferring genes into LH265 plant for desired agronomic traits such as herbicide resistance, and resistance to insect resistance, and male sterility trait (columns 3-4). Since Applicant has not disclosed specific morphological and physiological characteristics for the claimed F1 or other types of hybrid and subsequent generation plants /seeds, the claimed plants are expected to be indistinguishable from those of the prior art, especially since the second parent plants involved in the crossing are unknown. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Therefore, the claimed invention is anticipated by or, in the alternative, is obvious over the prior art, absent evidence to the contrary.

Remarks

No claim is allowed.

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Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

4/28/03

Mai


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER